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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/054,660	04/03/1998	PHILIP E. EGGERS		2890

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/054,660

Applicant(s)

EGGERS ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41, 43-58 and 60-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43-58 and 60-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/7/05 (x6)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's amendments and comments, received November 9, 2005, have been fully considered by the examiner. In particular, applicant has indicated that a replacement sheet page 21/21 containing Figure 23 is enclosed with the November 9, 2005 response. However, the Office shows no receipt of this figure. The following is a complete response to the November 9, 2005 communication.

Drawings

The drawings are objected to because Figure 23 (drawing sheet 21) is missing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 41 recites "inducing a discharge of energetic electrons and photons" at line 5, then recites "directing the energetic electrons and protons". It is not clear if the proper term should be "protons" or "photons", however, the terminology should remain consistent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 43-45, 47, 48, 51-58, 60, 61, 65-73 and 76-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al (5,389,096) in view of the teachings of Swartz et al (5,902,289) and Bales et al (4,682,596).

Aita et al disclose a laser catheter device for performing PMR procedures. The catheter is advanced percutaneously into the ventricle of a heart and then used to form channels within the heart wall. Aita et al fail to specifically disclose the use of electrosurgical energy as the treatment energy, or of the use of an electrically conductive fluid with the electrosurgical energy. The particular channel size and shape are deemed to be obvious considerations for one of ordinary skill in the art and dependent on the need of a given procedure.

Swartz et al disclose another cardiac treatment catheter apparatus. In particular, Swartz et al teach that it is generally known in the art to substitute various well-known energy modalities in a cardiac ablation catheter. In particular, Swartz et al teach that it is known to use either laser or RF energy for ablating cardiac tissue (col. 11, lines 3-12). Swartz et al, however, does not specifically disclose the use of a conductive fluid in combination with the use of RF energy.

As addressed in the previous Office action, Bales et al disclose another RF catheter for treating cardiac tissue, including revascularizing tissue. In particular, Bales et al teach that it is known to provide the catheter with a variety of electrode arrangements including monopolar (i.e. a single electrode on the catheter and a remote return electrode) or bipolar (i.e. an active and a return electrode on the catheter) configurations. Further, Bales et al specifically teach of providing saline solution to the tissue site and of providing suction to remove fluid and debris from the treatment site.

With regard to the limitations of "including a discharge energetic electrons and photons" and "directing the energetic electrons and protons", the examiner maintains that the RF systems disclosed by Swartz et al and/or Bales et al would inherently perform such a function. Applicant has disclosed no particular structure and/or energy level beyond what is typically known and used in the art. That is, there is no apparent critical voltage level and/or structure for the electrodes that would allow applicant's system to perform such a function, and which would suggest that the prior art RF systems do not operate in the same manner.

It is noted that the combination of the Swartz et al teaching with the Aita et al system has been addressed in the previous Office action. To have provided the Aita et al system, as modified by the teaching of Swartz et al, with any well known electrode arrangement would have been an obvious modification for one of ordinary skill in the art, particularly since Bales et al teach of the various well-known electrode arrangements provided on cardiac ablation catheters. To have further provided the Aita et al system with a saline line and a suction means to provide fluid flushing and removal would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Bales et al.

Claims 49, 50, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al ('096), Swartz et al ('289) and Bales et al ('596) as applied to the claims above, and further in view of the teaching of Aita et al (5,380,316).

The combination of the Swartz et al and Bales et al teachings with the Aita et al system has been addressed previously. Aita et al ('096) discloses percutaneously accessing a ventricle of the heart to perform the procedure, but fails to specifically disclose performing the procedure from the epicardium side of the heart.

Aita et al ('316) disclose essentially the same procedure as shown in the ('096) patent, but teach that it is known to perform the revascularization from the epicardial side of the heart.

To have performed the Aita et al ('316) procedure from the epicardial side of the heart would have been an obvious alternative to one of ordinary skill in the art,

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particularly since Aita et al ('096) teach that it is known to perform the procedure epicardially.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al ('096), Bales et al ('596) and Swartz et al ('289) as applied to the claims above, and further in view of the teaching of Murphy-Chutorian (5,891,133).

The combination of the Swartz et al and Bales et al teachings with the Aita et al system has been addressed previously. Aita et al ('096) discloses percutaneously accessing a ventricle of the heart to create channels in heart tissue, but fails to specifically disclose inserting a prosthesis (i.e. stent) into the channel to maintain the patency of the channel.

Murphy-Chutorian disclose a device for the same procedure (i.e. TMR), and specifically teach that it is advantageous to insert a radially expandable stent into the revascularized tissue.

To have provided the Aita et al system with a stent or prosthesis for maintaining the patency of the newly created channel would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Murphy-Chutorian.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al ('096), Bales et al ('596) and Swartz et al ('289) as applied to the claims above, and further in view of the teaching of Mueller et al (5,766,164).

The combination of the Swartz et al and Bales et al teachings with the Aita et al system has been addressed previously. Aita et al ('096) discloses percutaneously accessing a ventricle of the heart to create channels in heart tissue, but fails to specifically disclose making curved or U-shaped channels.

Mueller et al disclose another system for creating channels in cardiac tissue (i.e. TMR). In particular, Mueller et al teach that it is advantageous to create curved and/or u-shaped channels (see Figures).

To have used the Aita et al system to create curved and/or U-shaped channels to improve blood perfusion in cardiac tissue in the TMR procedure would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Mueller et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 43-58 and 60-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S.

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Patent No. 5,873,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 41, 43-58 and 60-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S.

Patent No. 5,683,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 41, 43-58 and 60-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-104 of U.S.

Patent No. 5,697,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 41, 43-58 and 60-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-56 of U.S.

Patent No. 5,697,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 41, 43-58 and 60-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,032,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

Claims 41, 43-58 and 60-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/347,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor variations in the claimed method steps are deemed obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed November 9, 2005 have been fully considered but they are not persuasive.

The arguments presented by the applicant assert simply that the claims define over the prior art because "none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency voltage to the active electrode terminal and a return electrode and directing the energetic electrons and protons to volumetrically remove tissue" (page 13 of applicant's response). The examiner disagrees.

Applicant's specification does not disclose any critical and/or unexpected voltage level that enables the instantly claimed invention to discharge "energetic electrons and photons" any differently than the prior art electrodes. That is, the known range of voltages used in electrosurgical procedures is generally very well known and used by the Bales et al and Swartz et al systems. These devices are deemed to inherently present electrodes that would discharge energetic electrons and photons/protons as would any conventional RF electrode system. As such, the examiner maintains that prior art reads on the claim language.

With regard to the Double Patenting rejections, the examiner had inadvertently rejected previously pending claims. The rejection now recites the currently pending claims.

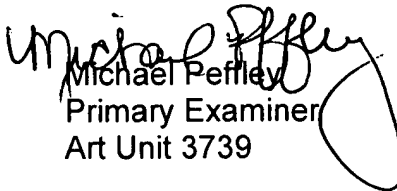
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Perley
Primary Examiner
Art Unit 3739

mp
January 17, 2006